#### **National Patient Safety Goals**

## Eight Recommendations for Policies for Communicating Abnormal Test Results

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Pailures of communication and follow-up of abnormal diagnostic test results can lead to errors, adverse events, and liability claims.1-5 Therefore, The Joint Commission has prioritized safe and timely communication of critical test results as a National Patient Safety Goal (NPSG.02.03.01), "Report critical results of tests and diagnostic procedures on a timely basis."6 Although communication breakdowns are deemed largely preventable, this goal remains one of the most commonly cited areas of noncompliance in routine surveys.7 The evolving definition of "critical" results adds further complexity to the problem. In laboratory medicine, a critical (or panic) laboratory value represents a "pathophysiologic state at such variance with normal as to be life threatening if an action is not taken quickly and for which an effective action is possible."8(p. 709) It is now thought that this definition should include equally important but less time-sensitive "vital" values. 9-12

Emerging evidence highlights vulnerabilities in test-result communication practices along the entire spectrum of testresult abnormality and severity.<sup>5,13–17</sup> The risks of communication breakdowns apply not only to critical values but also to abnormal but non-life-threatening test results. The latter are especially pertinent in the outpatient setting. For example, many test results (for example, chest x-ray with a suspicious shadow), although neither immediately life threatening nor requiring immediate attention, require a response by the provider in a relatively short (1–2 week) period of time. These results may not warrant direct verbal communication to providers; other means of indirect communication such as secure fax, e-mail, or the electronic medical record (EMR) are appropriate for this intermediate level of urgency. In March 2009, the Veterans Health Administration (VHA) released a directive recommending that test results be communicated to providers "within a timeframe allowing prompt attention and appropriate action to be taken" and to patients so that "they

For editorial, see pages 224-225.

#### Article-at-a-Glance

Background: Health care organizations continue to struggle to ensure that critical findings are communicated and acted on in a timely and appropriate manner. Recent research highlights the risks of communication breakdowns along the entire spectrum of test-result abnormality, including significantly abnormal but nonemergent findings. Evidence-based and practical institutional policies must uphold effective processes to guide communication of abnormal test results. Eight recommendations for effective policies on communication of abnormal diagnostic test results were developed based on policy refinement at the Michael E. DeBakey Veterans Affairs Medical Center (Houston), institutional experience with test result management, and findings from research performed locally and elsewhere.

Key Facets of Effective Policies: Research findings on vulnerabilities in existing policies and procedures were taken into consideration. The eight recommendations are based on important refinements to the policy which clarified staff roles and responsibilities for test ordering, follow-up, and communication; defined categories of abnormal test results to guide appropriate follow-up action; and elaborated procedures for monitoring the effectiveness of test result communication and follow-up. Participation of key stakeholders is recommended to enhance buy-in from personnel and to help ensure the policies feasibility and sustainability.

**Conclusions:** The proposed recommendations for ensuring safe test-result communication may be potentially useful to a wide variety of institutions and health care settings. These practical suggestions, based on research findings and experiences with a previous policy, may be a useful guide for designing or amending policies for safe test-result communication in both inpatient and outpatient settings.

| Table 1. Types of Definitions Useful in the Introductory Section of a Policy |   |  |  |  |
|--|---|--|--|--|
| Term   | Description   |  |  |  |
| Critical test result   | Any result or finding that may be considered life threatening or that could result in severe morbidity            |  |  |  |
|  | and require urgent or emergent clinical attention   |  |  |  |
| Significantly abnormal test result   | Nonemergent, non-life-threatening results that need attention and follow-up action as soon as                     |  |  |  |
|  | possible, but for which timing is not as crucial as critical results. They generate a mandatory notifica-         |  |  |  |
|  | tion in the electronic health record but are not required to be reported verbally.                                |  |  |  |
| Critical tests   | Tests that require rapid communication of results, whether normal, abnormal, or critical                          |  |  |  |
| Read-back  | The process of an individual receiving the results of a critical or significantly abnormal result or a criti-     |  |  |  |
|  | cal test by writing down and reading back the information to the individual providing this information            |  |  |  |
| Diagnostic areas   | Pathology and laboratory medicine, imaging, cardiology, and other diagnostic areas as defined by the organization |  |  |  |

may participate in health care decisions." Although apparently reliable electronic systems are used to communicate abnormal test results, breakdowns in test result follow-up persist. For example, our recent work on automated EMR–based notifications of diagnostic test results within the Department of Veterans Affairs (VA) outpatient setting showed that 7% of abnormal laboratory results and 8% of abnormal imaging results lacked timely follow-up despite evidence of transmission to providers. This is consistent with work in non–VA settings, where approximately 7% of abnormal diagnostic test results were either never communicated to the patient or the disclosure was undocumented.

Therefore, evidence-based and practical institutional policies must uphold effective processes to guide communication of abnormal test results.<sup>21</sup> In 2004, we implemented a policy at our institution (Michael E. DeBakey VA Medical Center, Houston) in response to two separate incidents of small lung nodules detected on chest x-rays that went on to develop into unresectable lung carcinomas in the absence of any follow-up. We recently revised this policy in light of new guidance from the VA Central Office, updated Joint Commission National Patient Safety Goal requirements, and evidence from both within and outside our institution. This article describes the rationale of our institutional policy and provides general recommendations, on the basis of our previous work, other literature, and sound clinical practice, for creating or updating similar policies at other institutions.

## Recommendation 1. Policies Should Be Introduced with Clear Definitions of Key Terms

Test-result policies should provide key definitions up front. This not only lends credibility to the policy but also standardizes understanding across many users. Although the Joint

Commission, the College of American Pathologists, and the Clinical Laboratory Improvement Act all require that laboratories and hospitals have procedures in place for immediately conveying critical results to the responsible provider,<sup>22–24</sup> what constitutes "critical" should be defined explicitly.

For example, in our new policy a section of key terms appears immediately after the statement of purpose (Table 1, above), and specific critical values for laboratory and pathology tests are listed in a set of appendices. Our policy also distinguishes critical results from "significantly abnormal" test results, such as positive cancer screens, that may require timely action but that are essentially nonemergent. It is important that policies address both degrees of abnormality to ensure that appropriate clinical responses occur within a reasonable time line. Our work has shown that many imaging results lacking timely follow-up were "suspicious for a new cancer diagnosis," and providers may perceive a lack of urgency for these types of test results because they may have less immediate implications.<sup>20,25</sup>

## Recommendation 2. Policies Should Clearly Outline Provider Responsibilities

Ambiguous responsibility for test result follow-up can threaten patient safety.<sup>20</sup> For example, we found cases in which an ordering provider other than the primary care physician (PCP)—that is, a specialist or covering provider—believed that follow-up was the PCP's responsibility; meanwhile, the PCP, who did not order the test, believed otherwise, and no follow-up action was taken. Clarifying providers' responsibilities for follow-up is crucial in this scenario and in other situations when test results are communicated to more than one provider. We found that our institution's well-intentioned "dual notification" feature actually increased the odds that abnormal imaging results would not receive timely follow-up.<sup>20</sup>

Our policy has since been clarified to identify the ordering

provider—regardless of specialty or routine relationship to the patient—as the person with whom responsibility rests for initiating follow-up of abnormal results.

#### Recommendation 3. Policies Should Specify Procedures for Fail-Safe Communication of Abnormal Test Results

Ensuring delivery of test results can be challenging. It is sometimes difficult to identify the correct ordering provider or his or her contact information or to ensure he or she received the message. <sup>25,26</sup> Institutions must ensure that personnel involved in reporting test results have access to regularly updated contact information for ordering providers and their surrogates. In addition, transmission of information must be accompanied by backup procedures to ensure delivery. Computerized order entry and the use of an EMR may overcome some of these challenges. <sup>26</sup> For instance, critical and significantly abnormal results generate a "mandatory" alert, that is, the alert cannot be customized to be turned off by the receiving provider.

Processes at our institution allow providers to assign surrogates for both electronic and verbal notifications. Within the EMR, patients are assigned to a permanent staff PCP, and every mandatory test result is also sent to the PCP if he or she is not the ordering provider (with clear responsibilities for follow-up, as described). Similarly, trainees are assigned a supervising permanent staff physician so that every mandatory test-result alert is automatically transmitted to the staff physician in the trainee's absence; this practice is well accepted and works well given the duty hour requirement for trainees.

Clear identification and read-back procedures for verbal notification ensure accurate transmission. For example, our policy for reporting critical laboratory values states that clinical laboratory personnel must identify themselves, state the emergency nature of the call, verify the name of the person receiving the report (either the ordering provider or his or her designee or surrogate), and give the name of the laboratory test and the test results. The person receiving the report must then read back the patient's name and the critical result. This interaction must be documented with the date and time of the call and the full names of both parties. Per our institutional policy, failed attempts to verbally communicate critical results to the responsible provider are documented on the Critical Values Documentation Form. In general, we have found laboratory result read-back procedures somewhat easier to implement because of their almost invariably numerical critical results.

For after-hours situations, structured algorithms with "escalation to supervisory level" provide guidance for sustaining

communication attempts and avoiding loss of follow-up after repeated failures to reach the ordering or surrogate provider. These algorithms may include the use of licensed caregivers, such as nurses and mid-level providers, to receive results.<sup>27</sup> Such algorithms are especially useful for tests from outpatient settings, which traditionally take twice as long to report,<sup>27</sup> or when test results return after the patient has been discharged from the hospital, a particular area of vulnerability.<sup>28</sup> Examples of communication algorithms from our policy are provided in Figure 1 and Figure 2 (available in online article).

#### Recommendation 4. Policies Must Define Verbal and/or Electronic Reporting Procedures for Both Critical and Significantly Abnormal Laboratory, Imaging, and Other Test Values

For any potentially life-threatening result, verbal notification of abnormal values is far more likely than electronic notification to initiate a response and is therefore a necessity. For significantly abnormal results, at minimum some form of mandatory electronic notification is necessary. Such as alerting the provider through the EMR, an alphanumeric pager, or a secure fax. EMR systems can be configured to generate an alert automatically on entry of test results that meet or exceed certain preset values (for example, prostate-specific antigen [PSA] > 15 ng/mL). Automated notification ensures that significantly abnormal findings are communicated consistently, but it does not eliminate certain gray areas, such as abnormal findings that do not really meet the threshold for a mandatory alert. Furthermore, notifications of repeat critical or abnormal values may not be necessary.

Certain details of the procedures that we find useful for reporting diagnostic tests are now outlined.

Laboratory and Pathology Results. Our institutional policy establishes the clinical executive board's responsibility for creating and maintaining a list of tests and their defined high and/or low critical values for both verbal and mandatory electronic notification. This list is subject to review at least annually. Many laboratories already use a critical value list, and several references are available in the literature, 12,30,31 although institutions may need to customize their own laboratory and pathology lists. 9,10,32,33 Our policy requires that critical results be transmitted to the ordering provider both verbally (that is, by telephone or face to face) and through the EMR. Any new pathologically confirmed malignancy in a patient with no existing definitive diagnosis of malignancy is communicated to the ordering provider through the EMR and, for some malignancies, verbally as well. Selected nonemergent but significantly

Table 2. Significantly Abnormal Laboratory Values That Trigger Mandatory Electronic Notification\*

| Test           | Reportable High |
|----------------|-----------------|
| Occult Blood   | Positive        |
| PSA, Total     | > 15 ng/mL      |
| TSH            | > 15 uIU/mL     |
| Hemoglobin A1C | > 15%           |
| HCV AB         | Positive        |
| HCV-PCR        | Positive        |
| Western Blot   | Positive        |
| RPR            | Reactive        |
| BUN            | ≥ 40 mg/dL      |
| Creatinine     | ≥ 2 mg/dL       |
| CPK            | ≥ 1,000 U/L     |

<sup>\*</sup> PSA, prostate-specific antigen; TSH, thyroid-stimulating hormone; Hemoglobin A1C, glycosolated hemoglobin; HCV AB, hepatitis C virus antibody; PCR, polymerase chain reaction; RPR, rapid plasma reagin; BUN, blood urea nitrogen; CPK, creatine phosphokinase.

abnormal laboratory results trigger a mandatory alert in the EMR (Table 2, page 229).

Diagnostic Imaging Results. Radiologists are now strongly advised to expedite reports that indicate significant or unexpected findings to ordering providers "in a manner that reasonably ensures timely receipt of the findings." Radiologists and nuclear medicine physicians at our institution use a voice-recognition dictation system when reporting their interpretations in the EMR. Reporting priority is given to tests requested as "stat" and "urgent." An official interpretation (final report) is generated and archived as soon as possible following any examination, procedure, or officially requested consultation, regardless of where the exam was performed.

Pertinent diagnostic reporting codes (Table 3, page 230) are applied to the majority of imaging studies, with negative studies left uncoded. These codes, in turn, generate automated notifications to the provider in the EMR and have been adopted by other VA facilities in our south-central network. Verbal notification is required in cases of critical abnormalities and new reportable infectious abnormalities, and the details of the notification (date, time, and provider name) are documented in the final imaging report. In response to the VHA directive, <sup>13</sup> all VA facilities are developing abnormal diagnostic imaging codes.

Imaging reports are sometimes amended by a radiologist, especially when the test was initially read by a resident after hours. Any amendment to a report generates a mandatory notification to the ordering provider per our policy. Our policy also addresses standards for communicating results of studies performed outside our institution. Specifically, patients at our institution who require mammography are referred to providers

in the community who have agreed to communicate their findings according to our policy. A separate set of diagnostic codes are used to trigger electronic and/or verbal notification of abnormal results from these studies (Table 3). The mammography codes are now standardized across the VA.

Other Abnormal Test Results. Policies should be tailored to address the needs of the institution and need not be limited to imaging and laboratory results. Because our patients tend to be older and at higher risk for cardiac problems, we have implemented procedures to streamline reporting of certain electrocardiogram and echocardiogram findings when the interpreting cardiologist finds a critical abnormality.

#### Recommendation 5. Policies Should Specify "Critical Tests" and Acceptable Length of Time Between Their Ordering and Reporting

"Critical tests" are those that require communication of results regardless of finding (for example, normal, abnormal, or critical). The term was introduced in a Joint Commission National Patient Safety Goal in 2008 for implementation in 2009.

At our institution, a critical imaging test is defined as any imaging study requested as a STAT order, called in to the radiologist by telephone as a STAT exam and reading. These orders must clearly provide the complete contact information for the ordering provider. To determine whether these studies are being completed and reported within acceptable time limits, our policy identifies three such critical tests for routine monitoring of timeliness, as follows:

- 1. Radiograph in the operating room for retained foreign body (completed within 30 minutes of order and reported within time lines defined in other policies)
- 2. Ultrasound examination to rule out ectopic pregnancy (completed within 60 minutes of order and reported within 60 minutes of completion)
- 3. Post-trauma cross-table radiograph of the cervical spine in the emergency department (completed within 60 minutes of order and reported within 60 minutes of completion)

All pathology frozen sections are also considered critical tests and are monitored for timeliness of completion and reporting.

# Recommendation 6. Policies Should Define Time Lines Between the Availability of Test Results and Patient Notification, and Institutions Should Specify Preferred Mechanisms for Patient Notification

Recommended timeliness standards for patient notification are available for certain types of critical results (ranging from 15

| Table 3. Diagnostic Reporting Codes for Imaging Studies* |   |                                  |                                      |
|--|---|----------------------------------|--------------------------------------|
| Code   | Diagnostic Reporting Code Definition  | Mandatory<br>Verbal Notification | Mandatory<br>Electronic Notification |
| 201  | Critical Abnormality  |                                  |                                      |
|  | Any new finding that may be considered life threatening or could result in severe |                                  |                                      |
|  | morbidity and require urgent or emergent clinical attention (e.g., cerebral       |                                  |                                      |
|  | hemorrhage, pneumothorax, pulmonary embolism, significant misplacement            |                                  |                                      |
|  | of tubes or catheters)  | Y                                | Υ                                    |
| 202  | New Reportable Infectious Abnormality   |                                  |                                      |
|  | Active tuberculosis or other reportable infectious disease that requires          |                                  |                                      |
|  | urgent follow-up  | Y                                | Υ                                    |
| 203  | Findings Suspicious for New Malignancy  |                                  |                                      |
|  | An unexpected abnormality that is suspicious or highly suggestive of malignancy   | N                                | Υ                                    |
| 204  | Abnormality   |                                  |                                      |
|  | An abnormality or unexpected finding that is not considered to be an urgent       |                                  |                                      |
|  | and immediate life-threatening finding but needs attention and follow-up action   |                                  |                                      |
|  | as soon as possible (e.g., acute fracture, new pneumonia, aortic aneurysm)        | N                                | Υ                                    |
| Mamn   | nography Diagnostic Reporting Codes   |                                  |                                      |
| 1104   | BI-RADS 4 Mammogram   |                                  |                                      |
|  | Suspicious abnormality; biopsy should be considered                               | Υ                                | Y                                    |
| 1105   | BI-RADS 5 Mammogram   |                                  |                                      |
|  | Highly suggestive of malignancy; appropriate action should be taken               | Υ                                | Y                                    |
| 1106   | BI-RADS 6 Mammogram   |                                  |                                      |
|  | Known biopsy-proven malignancy; appropriate action should be taken                | Υ                                | Y                                    |
| * Y, yes   | s; N, no; BI-RADS, Breast Imaging–Reporting and Data System.                      |                                  |                                      |

minutes to 60 minutes), but these may need to be customized to some extent by institutions.<sup>21,27</sup> For other significantly abnormal results, time frames are less well defined. One exception is VHA Directive 2009-019, which requires communication of non–life-threatening outpatient test results to patients no later than 14 calendar days from the date when results are available to the ordering provider.<sup>13</sup>

Policies should provide specific guidance on preferred means of communicating with patients or their designated representatives (for example, in-person, telephone, written, or secure portal). Although communication of test results through secure e-mail or Web-based portals has several advantages, previous research has shown that physicians tend to favor direct reporting to patients only when test results are normal, have less diagnostic severity, or have less potential for emotional impact.<sup>35</sup> Nevertheless, best practices in patient notification are evolving and are significantly likely to influence practice in future.

#### Recommendation 7. Policies Must Be of "Real World" Value and Written with Feedback from Key Stakeholders

Policies are often geared toward regulatory compliance rather

than operational value. Implementation of a sustainable and effective policy hinges on education and reinforcement of its users, which necessitates a concise, user-friendly, and easily referenced document. Policies should reflect feedback from representatives of key stakeholders including providers (both primary care and subspecialists), laboratory personnel, radiologists, quality improvement personnel, and residency training program personnel (in teaching institutions).

At our institution, the diagnostic committee [including H.S., M.S.V.] represents many of the aforementioned clinical and administrative stakeholders involved with management of diagnostic tests and is responsible for the content of the policy. This committee met every month during a six-month period in 2009 to reach consensus on certain new changes. Members sought current literature for guidance and solicited feedback from other stakeholders when necessary. We also obtained buyin from personnel who were being given responsibility for afterhours notification. For example, we learned that when the ordering or surrogate provider is not available after hours, reporting emergent results to the on-call senior resident may not be the best option, because it might add to his or her work load and thereby jeopardize compliance with Accreditation Council for Graduate Medical Education regulations.<sup>36</sup> Our

critical value list was made current and finalized after consultation with relevant services and subspecialists. Recommendations were forwarded to leadership for feedback and approval, after which they were officially implemented.

#### Recommendation 8. Policies Should **Establish Responsibilities for Monitoring** and Evaluating Communication Procedures

Although electronic notification provides a means of ensuring that test results are transmitted, it provides no guarantee of follow-up. Thus, communication processes must be audited to ensure not only compliance with reporting procedures but also the timeliness of follow-up actions on abnormal test results, including patient notification. Monitoring and evaluation procedures must take into account work flow and practical management issues at the receiving end of the communication. In studies of both laboratory and imaging abnormal results, we found that electronically "acknowledged" and nonacknowledged test-result alerts were equally associated with a lack of timely follow-up. 19,20 When we discussed this with providers, they expressed the need for better systems to track follow-up actions and patient notification. We plan to address these needs in future work.

Finally, institutions must continuously learn from the intended and unintended consequences of their policies over time and identify failure modes and actual performance. Particularly when data suggest a potential system failure, the enlistment of end users to provide feedback on system performance is key for continuous quality improvement. For instance, in another study we found that system interventions including mandatory notification to improve follow-up of positive fecal occult blood test results did not dramatically reduce the high proportion of positive tests with no documented follow-up after two weeks.<sup>17</sup> Through consultation with end users and representatives from administration and information technology, we discovered and fixed a glitch in our software that had prevented the transmission of a certain subset of abnormal test results.26

#### **Conclusions**

We offer eight recommendations for health care institutions to design effective policies for ensuring safe and timely test-result communication. These recommendations are based on our recent work, experiences with a previous policy, and current literature, and they address the Joint Commission's National Patient Safety Goal (NPSG.02.03.01) of ensuring safe communication of critical diagnostic test results. We caution that many lessons learned are from experiences at a single VA facility and may not fully generalize to other VA or non-VA facilities. Although policy content may overlap between VA facilities because they respond to the VHA Directive, details of policy implementation are not standardized across the VA system, and facilities may design policies and procedures to best address local needs. However, certain best practices could potentially be standardized and applied across VA facilities in the future without eliminating important areas of flexibility. There is already a move toward standardizing the use of certain computerized codes used by radiologists across our region and nationally. Moreover, the principles that underlie these recommendations can be useful for a wide variety of institutions and health care practices and apply to inpatient and outpatient care, EMR and non-EMR users, and private and public settings. Thus, despite the limitations of our work, some of these practical suggestions and best practices may be a useful guide for institutions to design or amend their policies for safe test-result communica-

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Figure 1. Algorithm for Outpatient Critical Value Reporting Process

Figure 2. Algorithm for Inpatient Critical Value Reporting Process

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#### **Algorithm for Outpatient Critical Value Reporting Process**

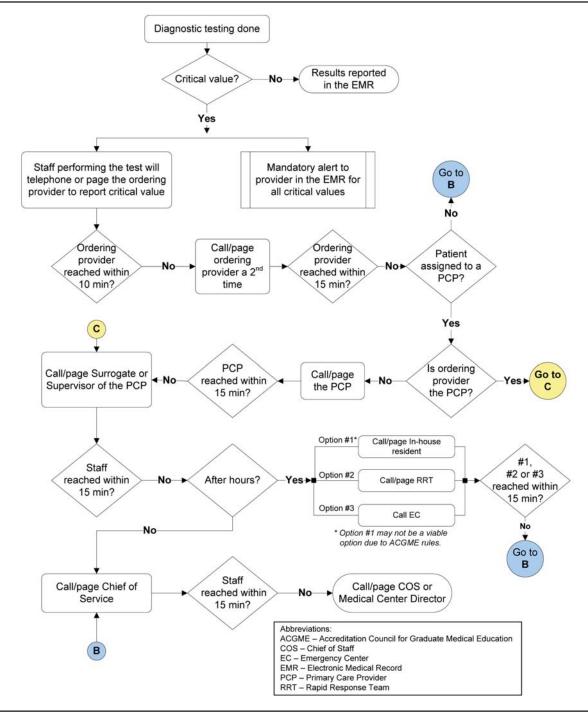


Figure 1. The algorithm for the outpatient critical value reporting process is shown. If the ordering provider or primary care provider is not reached, the cascade is escalated to the facility leadership.

## Online-Only Content

#### **Algorithm for Inpatient Critical Value Reporting Process**

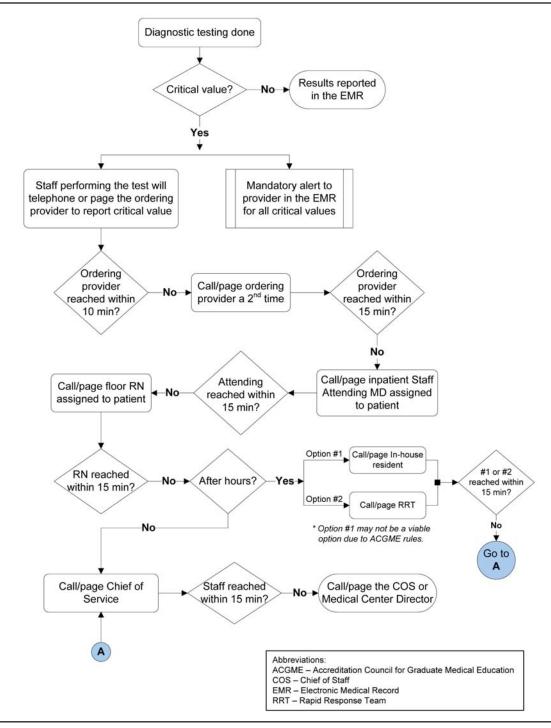


Figure 2. The algorithm for the inpatient critical value reporting process is shown. If the ordering provider or inpatient staff attending is not reached, the cascade is escalated to the facility leadership.